

510(k) SUMMARY OF SAFETY AND EFFECTIVENESS  
(Pursuant to Section 12, Safe Medical Devices Act of 1990)

1. Identifying Information:

**Submitter:** Medtronic Vascular  
37A Cherry Hill Drive  
Danvers, MA 01923

**Contact Person:** Karen A. Brozowski.  
Regulatory Affairs Manager  
(978) 739-4143

2. **Classification Name:** Catheter, carotid, temporary, for embolization capture (21 CFR Part 870.1250) Product Code NTE

3. **Proprietary Name:** GuardWire® Temporary Occlusion and Aspiration System

4. **Name of Predicate Devices:**

GuardWire® 3-6 Temporary Occlusion and Aspiration System	K023878
6F Export® Catheter	K030201
Export® XT Catheter	K061958
RX ACCUNET™ Embolic Protection System	K052166
SpideRX® Embolic Protection Device	K052659
The Emboshield® Embolic Protection System	K052454

5. **Description:**

The GuardWire® Temporary Occlusion and Aspiration System is comprised of four principal components: the GuardWire Temporary Occlusion Catheter, the EZ Adaptor device, the Export® Catheter, and the EZ Flator Inflation device.

The GuardWire Temporary Occlusion Catheter is a “balloon-on-a-hypotube-wire” catheter with a distal elastomeric occlusion balloon. It has a lubricious coating and a flexible radiopaque tip. The GuardWire Temporary Occlusion Catheter is packaged

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with an Introducer Sheath, an EZ Adaptor device, and an EZ Flator Inflation Device. The EZ Adaptor device is used exclusively with the GuardWire Temporary Occlusion Catheter for the purpose of controlled volumetric inflation and deflation of the temporary occlusion balloon.

The EZ Flator device is used exclusively with the GuardWire Temporary Occlusion Catheter during catheter preparation, inflation and deflation of the balloon. The EZ Flator device delivers a controlled volume when inflating the balloon to each occlusion size. It has an integrated deflation syringe used for catheter preparation and balloon deflation and has a reservoir for diluted contrast solution.

The Export Catheter is compatible with the GuardWire Temporary Occlusion Catheter and has a distal radiopaque tip marker and proximal Luer-lock port.

**6. Intended-Use:**

The GuardWire Temporary Occlusion and Aspiration System is indicated for use in carotid arteries to:

- Contain and aspirate embolic material (thrombus/debris) while performing angioplasty or stenting procedures.
- Facilitate placement and use of diagnostic or therapeutic catheters using the GuardWire Temporary Occlusion Catheter.
- To locally infuse/deliver diagnostic or therapeutic agents with or without vessel occlusion.
- The diameter of the artery where the occlusion balloon is placed should be between 3 and 6 mm.

**7. Summary Of Substantial Equivalence:**

The GuardWire 3-6 Temporary Occlusion and Aspiration System for carotid artery use is manufactured under the same conditions, using the same processes and materials as the legally marketed GuardWire predicate devices, K023878, K030201. In addition to being technologically equivalent to the GuardWire predicate devices, the indications for use are substantially equivalent the predicated devices described in K052454, K052659 and K052166. The safety and

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performance of the GuardWire 3-6 Temporary Occlusion and Aspiration System for use in carotid arteries is supported by the MAVERIC I & II clinical trials.

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

OCT 31 2007

Medtronic Vascular, Inc.  
c/o Ms. Karen A. Brozowski  
Regulatory Affairs Manager  
37A Cherry Hill Drive  
Danvers, MA 01923

Re: K072990  
Trade/Device Name: GuardWire Temporary Occlusion and Aspiration System  
Regulation Number: 21 CFR 870.1250  
Regulation Name: Percutaneous Catheter  
Regulatory Class: Class II (two)  
Product Code: NTE  
Dated: April 23, 2007  
Received: October 24, 2007

Dear Ms. Brozowski:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

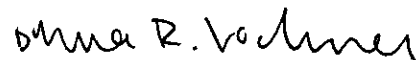
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,



Bram D. Zuckerman, M.D.  
Director

Division of Cardiovascular Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure

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## Indications for Use

510(k) Number: K072990

Device Name: GuardWire® Temporary Occlusion and Aspiration System

### Indications for Use:

The GuardWire Temporary Occlusion and Aspiration System is indicated for use in carotid arteries to:

- Contain and aspirate embolic material (thrombus/debris) while performing angioplasty or stenting procedures.
- Facilitate placement and use of diagnostic or therapeutic catheters using the GuardWire Temporary Occlusion Catheter.
- To locally infuse/deliver diagnostic or therapeutic agents with or without vessel occlusion.
- The diameter of the artery where the occlusion balloon is placed should be between 3 and 6 mm.

Prescription Use   X    
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use \_\_\_\_\_  
(21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

*Diana R. Volney*  
(Official Sign-Off)  
Director, Division of Cardiovascular Devices

510(k) Number K072990

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